

REMARKS

I. Support for the Amendments

Support for the amendments to the specification can be found throughout the specification, claims, and figures as filed. The amendments to the specification add sequence identifiers in compliance with United States practice and at the request of the Examiner. No new matter is added by virtue of these amendments. A substitute Sequence Listing is also provided.

Applicants have requested entry of the substitute Sequence Listing. In addition to the substitute copy of the diskette, a paper copy of the Sequence Listing is provided along with a Statement in Support of Filing and Submissions in Accordance with 37 CFR 1.821-1.825. The content of the attached paper copy and the attached computer readable copy of the Sequence Listing are the same. The entry of the Sequence Listing does not introduce new subject matter. SEQ ID: 63 – SEQ ID: 66 were already described in the specification.

Claims 1, 4, 6-7, 20-22, 24, 45, 48, 50, 52-53, 58-59, 62-64, 70-73, 75, and 78 are currently in the application. Claims 1, 4, 6-7, 20-22, 24, 45, 48, 50, 52-53, 58-59, 62, 72-73, 75, and 78 have been amended, and claims 2-3, 5, 8-19, 23, 25-44, 46-47, 49, 51, 54-57, 60-61, 65-69, 74, 76-77, and 79-82 have been canceled without prejudice to their pursuit in an appropriate continuation or divisional application.

Support for amended claims 1, 4, 6-7, 20-22, 24, 45, 48, 50, 52-53, 58-59, 62, 72-73, 75, and 78 can be found in the original specification and claims.

Additional support for amended claims 1, 4, 6-7, 20-22, 24, 45, 48, 50, 52-53, 58-59, 62, 72-73, 75, and 78 can be found, e.g., on page 43, lines 14-29; on page 44, lines 9-24; from page 44, line 31, to page 47, line 13; on page 48, lines 7-10 and 23-26; on page 49,

lines 11-14 and 19-22; on page 62, lines 3-29; from page 81, line 10, to page 85, line 7; and in the Experiments, Examples, and Figures.

II. Status of the Claims

Claims 1-82 were originally in the application. Claims 1-82 were subject to an Election/Restriction Requirement, and Group II was elected with traverse.

Claims 1, 4, 6-7, 20-22, 24, 45, 48, 50, 52-53, 58-59, 62-64, 70-73, 75, and 78 are currently in the application. Claims 1, 4, 6-7, 20-22, 24, 45, 48, 50, 52-53, 58-59, 62, 72-73, 75, and 78 have been amended, and claims 2-3, 5, 8-19, 23, 25-44, 46-47, 49, 51, 54-57, 60-61, 65-69, 74, 76-77, and 79-82 have been canceled without prejudice to their pursuit in an appropriate continuation or divisional application.

III. The Priority Claim

Applicants respectfully request that the Examiner acknowledge the priority claim.

IV. The Information Disclosure Statement

Applicants thank the Examiner for acknowledging the Information Disclosure Statements, but note that the two foreign patent documents cited therein were neither initialed nor crossed out. Applicants respectfully request clarification on this point.

V. The Objections to the Drawings

The Examiner has objected to the drawings. Applicants have amended the Brief Description of the Drawings in the specification to add the requested sequence identifiers in accordance with the Examiner's suggestion.

VI. The Objections to the Specification

The Examiner has objected to the specification:

The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO) be made in the specification and claims wherever a reference is made to that sequence. Specifically, the text in line 9 on page 185 and in lines 26 to 28 on page 189 of the instant specification describes amino acid sequences without employing the required sequence identifier. Correction is required. See M.P.E.P. 2422.03. [Par. 6; p. 6.]

Applicants have amended the specification accordingly.

VII. The Objection to Claims 16, 18, 22-27, 35, 37-44, and 76 is Accommodated in Part and Rendered Moot in Part

The Examiner has objected to claims 16, 18, 22-27, 35, 37-44, and 76 under 37 C.F.R. §1.75(c), alleging improper form for multiple dependent claims being dependent on multiple dependent claims.

Claims 16, 18, 23, 25-27, 35, 37-44, and 76 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants have amended claims remaining 22 and 24 accordingly to reduce the multiple dependency and respectfully request consideration of these claims accordingly.

VIII. The Objection to Claims 2, 46, and 62 is Accommodated in Part, Traversed in Part, and Rendered Moot in Part

The Examiner has objected to claims 2, 46, and 62 under M.P.E.P. §803.02, alleging recitation of an improper Markush group. The Patent Office alleges:

The multiple sequences recited in these claims do not reflect a common inventive concept because they lack a common utility that is based upon a common structural feature or combination of features that distinguishes them as a group from the prior art. For example, the only common feature of the peptides recited in sections 2 and 3 of claim 62 is the RF amide motif that was well known in the prior art, as disclosed on page 2 of the instant specification. [Par. 3, p. 2.]

Claims 2 and 46 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants have amended claim 62 to remove all peptides except for sections 1 (amino acid residues 81 to 92 of SEQ ID NO: 1) and 3 (amino acid residues 124 to 131 of SEQ ID NO: 1; re-numbered as 2). Applicants acknowledge that the species election was for SEQ ID NO: 8 (amino acid residues 81 to 92 of SEQ ID NO: 1), but they respectfully submit that the partial peptide of amino acid residues 81 to 92 and the partial peptide of amino acid residues 124-131 share not only the common structural features of the RF amide motif, but also similar biological activity with respect to stimulating prolactin secretion (see, e.g., Examples 10 and 21).

Applicants respectfully request consideration of remaining claim 62 accordingly.

IX. The Objection to Claims 3-7 and 47-57 is Accommodated in Part and Rendered Moot in Part

The Examiner has objected to claims 3-7 and 47-57 under 37 C.F.R. §1.75(c) as being of improper dependent form, alleging that they fail to further limit the subject matter of a previous claim.

Claims 3, 5, 47, 49, 51, and 54-57 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants have amended claims 1 and 45 with respect to residues 81 to 92 or residues 124 to 131 of SEQ ID NO: 1 (in addition to amendments made to claims 4, 6-7, 48, 50, and 52-53) and submit that claims remaining 4, 6-7, 48, 50, and 52-53 are now in proper dependent format. Applicants respectfully request consideration of these claims.

X. The Rejection of Claims 3, 7, 20, 21, 47, 52-59, 77, and 78 under 35 U.S.C. §112, First Paragraph, with Respect to Enablement is Rendered Moot

The Examiner has rejected claims 3, 7, 20-21, 47, 52-59, and 77-78 under 35 U.S.C. §112, first paragraph, alleging failure to comply with the enablement requirement. Applicants respectfully disagree, but have made a series of amendments to render the rejection moot.

The Patent Office alleges in pertinent part:

In so far as the instant claims encompass a "partial peptide" of SEQ ID NO:1 or 8 comprising anything other than residues 81 to 92, 101 to 112 or 124 to 131 of SEQ ID NO:1, the instant specification provides absolutely no reasonable

expectation that any other portion of SEQ ID NO:1 has any biological activity....

Because there is no evidence or sound scientific reasoning provided by the instant specification to support a conclusion that all or a specific portion of the amino acid sequence of SEQ ID NO:1, other than those three portions containing the art recognized RF amide motif, will stimulate prolactin secretion in a mammal, an artisan cannot "predict by resort to known scientific law" that a particular "partial peptide" will have the required activity. [Par. 8, p. 7.]

Claims 3, 47, 54-57, and 77 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants have amended claims 1, 45, 52-53, and 78 with respect to residues 81 to 92 or residues 124 to 131 of SEQ ID NO: 1 (in addition to amendments made to claims 7, 20, 21, and 58-59). The reasoning of the Patent Office (quoted *supra*) implies that the instant specification sufficiently describes the activity of partial peptides comprising residues 81 to 92, 101 to 112, or 124 to 131 of SEQ ID NO: 1.

Applicants respectfully submit that remaining claims 7, 20, 21, 52-53, 58-59, and 78 fulfill the requirements of 35 U.S.C. §112, first paragraph, thereby placing these claims in condition for allowance and request the Examiner's reconsideration accordingly.

XI. The Rejection of Claims 45-53, 55-59, 72, and 77-78 under 35 U.S.C. §112, First Paragraph, with Respect to Enablement is Traversed in Part, Accommodated in Part, and Rendered Moot in Part

The Examiner has rejected claims 45-53, 55-59, 72, and 77-78 under 35 U.S.C. §112, first paragraph, alleging failure to comply with the enablement requirement. Applicants respectfully disagree, but have made a series of amendments to render the rejection moot.

The Patent Office alleges in pertinent part:

These claims encompass subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In so far as these encompass "a prolactin secretion regulatory agent" having other than stimulatory activity, no such agent is described in the instant specification. There is absolutely no evidence of record that supports an assertion that one of the RF amide peptides described in the instant specification has inhibitory activity at any concentration. The theory that increasing concentrations of a receptor agonist will desensitize a receptor is not consistent with an inhibitory role for that agonist because desensitization and inhibition are not the same process nor do they produce the same result.... [Par. 9; p. 8.]

Claims 46-47, 49, 51, 55-57, and 77 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants have amended claims 45, 52-53, and 62 with respect to stimulating prolactin secretion (in addition to amendments made to claims 7, 20, 21, 58-59, and 78), e.g., by replacing "prolactin secretion regulatory agent" with --prolactin secretion stimulator--.

Moreover, Applicants respectfully submit that one of skill in the art would recognize that the prolactin stimulator of the present invention could be used, for example, as a galactosis stimulant for livestock mammals, because the relationship between prolactin and milk production is widely and clearly recognized by one skilled in the art (see Dorland's Illustrated Medical Dictionary, 28th ed. (1994); The Merck Index, 13th ed. (2001); The Merck Manual, 17th ed. (1999); and the Concise Oxford English Dictionary (1990); copies of all of which are provided herewith).

Applicants respectfully submit that remaining claims 7, 20, 21, 52-53, 58-59, and 78 fulfill the requirements of 35 U.S.C. §112, first paragraph, thereby placing these claims in condition for allowance and request the Examiner's reconsideration accordingly.

XII. The Rejection of Claims 1-7, 20-21, 45-59, 73-75, and 77 under 35 U.S.C. §112, Second Paragraph, is Traversed in Part, Accommodated in Part, and Rendered Moot in Part

The Examiner has rejected claims 1-7, 20-21, 45-59, 73-75, and 77 under 35 U.S.C. §112, second paragraph.

A. "Substantially the same"

The Patent Office alleges in pertinent part:

Claims 1 to 7, 20 and 21 are vague and indefinite because the metes and bounds of the limitation "substantially the same" is undeterminable when employed to define a structural element in a chemical compound. The term "substantially the same" is vague because it is not possible to determine at what point in deviation a different but similar sequence would cease to be "substantially the same" as the reference sequence. [Par. 10.1, pp. 9-10.]

Applicants have amended independent claim 1 to delete this phrase. Claims 4, 6-7, and 20-21 are dependent on claim 1. Claims 2-3 and 5 were also dependent on claim 1, but have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants respectfully submit that remaining claims 1, 4, 6-7, and 20-21 fulfill the requirements of 35 U.S.C. §112, second paragraph, thereby placing these claims in condition for allowance and request the Examiner's reconsideration accordingly.

B. “The Partial Peptide”

The Patent Office alleges:

Claim 7 is vague and indefinite because there is no antecedent basis for “the partial peptide”. [Par. 10.2, p. 10.]

Applicants have amended independent claim 1 to read “An isolated partial peptide...” Claim 7 is dependent on claim 1 and therefore includes the limitations of claim 1. Moreover, claim 7 has been amended to delete the phrase, “the partial peptide.”

Applicants respectfully submit that claims 7 fulfills the requirements of 35 U.S.C. §112, second paragraph, thereby placing this claim in condition for allowance and request the Examiner's reconsideration accordingly.

C. Steps Involved in the Method/Process

The Patent Office alleges in pertinent part:

Claims 73 to 75 and 77 provide for the use of a peptide, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. [Par. 10.3, p. 10.]

Applicants have amended claim 73 to recite steps in accordingly and submit that this claim is in condition for allowance.

Applicants traverse the rejection with respect to claim 75, which is not directed either to a method or to a process. Claim 75 is directed to a kit.

Claims 74 and 77 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants respectfully submit that remaining claims 73 and 75 fulfill the requirements of 35 U.S.C. §112, second paragraph, thereby placing these claims in condition for allowance and request the Examiner's reconsideration accordingly.

In view of the foregoing, Applicants respectfully submit that remaining claims 1, 4, 6-7, 20-21, 45, 48, 50, 52-53, 58-59, 73, and 75 fulfill the requirements of 35 U.S.C. §112, second paragraph, thereby placing these claims in condition for allowance and request the Examiner's reconsideration accordingly.

XIII. The Rejection of Claims 73-75 and 77 under 35 U.S.C. §101 is Traversed in Part, Accommodated in Part, and Rendered Moot in Part

The Examiner has rejected claims 73-75 and 77 under 35 U.S.C. §101. The Patent Office alleges in pertinent part:

Claims 73 to 75 and 77 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101....[Par. 11, p. 10; citation omitted.]

Applicants have amended claim 73 to recite steps in accordingly and submit that this claim is in condition for allowance.

Applicants traverse the rejection with respect to claim 75, which is not directed either to a method or to a process. Claim 75 is directed to a kit.

Claims 74 and 77 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants respectfully submit that remaining claims 73 and 75 fulfill the requirements of 35 U.S.C. §101, thereby placing these claims in condition for allowance and request the Examiner's reconsideration accordingly.

XIV. The Rejection of Claims 1-7, 20-21, 45-59, 62-64, and 70-72 under 35 U.S.C. §101 is Accommodated in Part and Rendered Moot in Part

The Examiner has rejected claims 1-7, 20-21, 45-59, 62-64, and 70-72 under 35 U.S.C. §101. The Patent Office alleges in pertinent part:

Claims 1 to 7, 20, 21, 45 to 59, 62 to 64 and 70 to 72 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims encompass a polypeptide as it occurs in nature. [Par. 12, p. 10.]

Applicants have amended claims 1, 45, 48, 50, 52-53, and 62 to recite “an isolated” peptide. Claims 2-7, 20-21, 46-59, 63-64, and 70-72 are dependent claims, and the limitations of one of the amended independent claims 1, 45, or 62 applies accordingly. Moreover, claims 2-3, 5, 46-47, 49, 51, and 54-57 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants respectfully submit that remaining claims 1, 4, 6-7, 20-21, 45, 48, 50, 52-53, 58-59, 62-64, and 70-72 fulfill the requirements of 35 U.S.C. §101, thereby placing these claims in condition for allowance and request the Examiner's reconsideration accordingly.

XV. The Rejection of Claims 1-2, 20-21, 45-46, 52, 54-59, and 77-78 under 35 U.S.C. §101 is Accommodated in Part and Rendered Moot in Part

The Examiner has rejected claims 1-2, 20-21, 45-46, 52, 54-59, and 77-78 under 35 U.S.C. §101. The Patent Office alleges in pertinent part: -----

Claims 1, 2, 20, 21, 45, 46, 52, 54 to 59, 77 and 78 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility and because they are drawn to an invention that is inoperative in its current form. These claims encompass a polypeptide comprising the entire amino acid sequence presented in SEQ ID NO:1 of the instant application. The instant application has provided a description of an isolated DNA encoding a preproprotein comprising four putative RF-amide-like polypeptides, and the preproprotein encoded thereby. Whereas Example 14 of the instant specification shows that the exogenous administration of a peptide consisting of residues 81 to 93 from the amino acid sequence presented in SEQ ID NO:1 of the instant specification stimulated the production of prolactin when administered to rats, there is absolutely no evidence that a protein comprising the entire amino acid sequence presented in SEQ ID NO:1 has any useful biological activity at all....

Because a peptide comprising SEQ ID NO:1 of the instant application has no demonstrable biological activity and the instant application fails to disclose a process of administering that peptide in a manner that results in it being processed into one or more active reagents that peptide has no specific utility as a clinical reagent....[Par. 13, pp. 10-12.]

Applicants have amended independent claims 1, 45, and 78 (and dependent claim 52) with respect to residues 81 to 92 or residues 124 to 131 of SEQ ID NO: 1. Claims 20-21 are dependent on claim 1, and claims 52 and 58-59 are dependent on claim 45, and the limitations of claim 1 and claim 45, respectively, apply to these dependent claims. Moreover, the reasoning of the Patent Office (quoted *supra* with respect to §112) implies that the instant specification sufficiently describes the activity of partial peptides comprising residues 81 to 92, 101 to 112, or 124 to 131 of SEQ ID NO: 1.

Claims 2, 46, 54-57, and 77 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants respectfully submit that remaining claims 1, 20-21, 45, 52, 58-59, and 78 fulfill the requirements of 35 U.S.C. §101, thereby placing these claims in condition for allowance and request the Examiner's reconsideration accordingly.

XVI. The Rejection of Claims 1-2, 20-21, 45-46, 52, 54-59, and 77-78 under 35 U.S.C. §112, First Paragraph, is Accommodated in Part and Rendered Moot in Part

The Examiner has rejected claims 1-2, 20-21, 45-46, 52, 54-59, and 77-78 under 35 U.S.C. §112, first paragraph, alleging that the claimed invention is inoperable. The Patent Office alleges in pertinent part:

Specifically, since the claimed invention is inoperable in currently available form for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. [Par. 14, p. 12.]

As noted in the previous section, Applicants have amended independent claims 1, 45, and 78 (and dependent claim 52) with respect to residues 81 to 92 or residues 124 to 131 of SEQ ID NO: 1. Claims 20-21 are dependent on claim 1, and claims 52 and 58-59 are dependent on claim 45, and the limitations of claim 1 and claim 45, respectively, apply to these dependent claims. Moreover, the reasoning of the Patent Office (quoted *supra* with respect to §112) implies that the instant specification sufficiently describes the activity of partial peptides comprising residues 81 to 92, 101 to 112, or 124 to 131 of SEQ ID NO: 1.

Claims 2, 46, 54-57, and 77 have been canceled without prejudice, and Applicants respectfully submit that the rejection is rendered moot with respect to these claims.

Applicants respectfully submit that remaining claims 1, 20-21, 45, 52, 58-59, and 78 fulfill the requirements of 35 U.S.C. §112, first paragraph, thereby placing these claims in condition for allowance and request the Examiner's reconsideration accordingly.

XVII. Additional Remarks by the Examiner

The Examiner also states:

The prior art of record did not disclose or suggest an isolated peptide comprising residues 81 to 92, 101 to 112 or 124 to 131 of SEQ ID NO:1 of the instant application. [Par. 15, p. 12.]

Applicants thank the Examiner for his remarks.

CONCLUSION

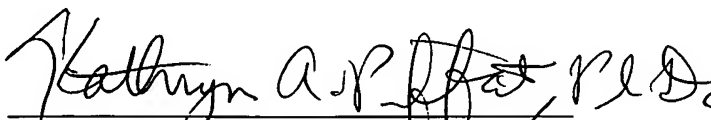
It is believed that all outstanding rejections have been addressed by this submission and that all the claims are in condition for allowance. If discussion of any amendment or remark made herein would advance this important case to allowance, the Examiner is invited to call the undersigned as soon as convenient.

In view of the foregoing amendments and remarks, the present application is respectfully considered in condition for allowance. An early reconsideration and notice of allowance are earnestly solicited.

Applicants respectfully request a one-month extension of time for the Amendment and accompanying materials and submit the appropriate fee herewith. If an additional extension of time is required, Applicants hereby request the Examiner to consider this a conditional petition for an additional extension of time. Although it is not believed that any additional fee (in addition to the fee concurrently submitted) is required to consider this submission, the Commissioner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

Respectfully submitted,

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